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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,196	04/14/2004	T. Douglas Mast	END5312USNP	5885
27805	7590	12/12/2007		
THOMPSON HINE L.L.P. Intellectual Property Group P.O. BOX 8801 DAYTON, OH 45401-8801				
EXAMINER				
PAPAPIETRO, JACQUELINE M				
ART UNIT		PAPER NUMBER		
3739				
MAIL DATE		DELIVERY MODE		
12/12/2007		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/824,196

Applicant(s)

MAST ET AL.

Examiner

Jacqueline Papapietro

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3. Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/21/2007, 11/08/2007, 8/30/2007, 8/17/2007, 8/02/2007, 7/11/2007, 7/10/2007.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3, 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castel (US 5413550) in view of Watkin et al (Non-Patent Literature).

Regarding claims 1 and 3, Castel discloses an ultrasound medical treatment system comprising: a) an ultrasound medical-treatment transducer (unit 2 and element 15); and b) a controller (4) which powers the transducer to deliver ultrasound at an ultrasound acoustic power for or beyond a determined treatment time to thermally ablate patient tissue (column 7 line 66- column 8 line 3), and at or above a determined ultrasound acoustic power for a treatment time to thermally ablate patient tissue (column 9 lines 47-48), wherein the controller determines the treatment time from a function (column 9 lines 29-45). Castel does not disclose determining an in vivo treatment time (or ultrasound acoustic power) from a function of experimentally-determined in vitro treatment time (or ultrasound acoustic power) for the transducer to deliver ultrasound at the ultrasound acoustic power (or for the treatment time) for the in vitro treatment time (or at the in vitro ultrasound acoustic power) to thermally ablate patient tissue in vitro. Castel also does not disclose that the mathematical function includes blood perfusion rate and patient tissue density.

Watkin teaches conducting studies on in vitro samples to define suitable exposure parameters for a high intensity focused ultrasound procedure in vivo

(abstract). Watkin teaches that a threshold exposure time was determined in vitro (page 193, "In Vitro Tissue Model"), and then the in vivo focal peak intensity was calculated in order to account for the acoustic loss in vivo (page 193, column 2, second full paragraph). Watkin further teaches that for exposure times of greater than approximately 3 seconds, blood perfusion rate and patient tissue density are critical for determining in vivo exposure parameters from in vitro exposure parameters (Discussion, pages 194 and 195).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Castel by using experimentally-determined in vitro treatment parameter in order to determine the in vivo treatment parameters with a function including blood perfusion rate and patient tissue density, as taught by Watkin, in the function disclosed by Castel, in order to safely and effectively ablate patient tissue in vivo.

Regarding claims 6 and 8, the claimed methods are anticipated by the normal use of the device as disclosed by Castel in view of Watkin.

Claims 2, 4, 7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castel in view of Watkin as applied to claims 1 and 3 above, and further in view of Hill et al (Non-Patent Literature).

Regarding claims 2 and 4, Castel in view of Watkin discloses the ultrasound medical treatment systems of claims 1 and 3, but is silent regarding specific mathematical equations. Hill teaches theoretical models of the formation of ultrasonic

focal lesions in tissue. The theoretical models include equations with the following variables/terms: time, patient tissue density, blood perfusion rate, temperature, and ultrasonic power deposition rate (page 260). Examiner takes the position that the claimed equations are manipulations of well-known equations that would be obvious to one skilled in the art. Arriving at the claimed equations using the teachings of Watkin and Hill requires only routine skill in the art. Therefore, at the time the invention was made it would have been obvious to one of ordinary skill in the art to have modified Castel in view of Watkin by using equations equivalent to the claimed equations for the controller to determine the in vivo treatment time and ultrasound acoustic power, as taught by Hill, in order to effectively ablate the target tissue.

Regarding claims 7 and 9, the claimed methods are anticipated by the normal use of the device as disclosed by Castel in view of Watkin in further view of Hill.

Response to Arguments

Applicant's arguments filed August 30, 2007 have been fully considered but they are not persuasive.

Examiner has read the entire Watkin reference, as requested by Applicant. However, Examiner still believes the combination of Castel and Watkin is obvious and discloses the claimed invention. The abstract of Watkin states, "in vitro experiments with excised porcine kidneys allowed determination of suitable exposure parameters to be tested in vivo." Applicant alleges that "this simply means that in vivo tests were done to verify in vitro experimentally-determined exposure parameters." Applicant has not

provided any support for this argument, and the Examiner disagrees. In the introduction Watkin clearly states that, "first the threshold for thermal damage in the porcine kidney was determined in vitro over a wide range of exposure conditions. Second, an in vivo large animal model was used to assess the accuracy and consistency of thermal injury." Examiner believes that the reference supports the teaching of determining in vivo treatment parameters from experimentally determined in vitro treatment parameters. Additionally, Watkin clearly teaches that for treatment times of greater than about 3 seconds, patient tissue density and perfusion rate are critical parameters in determining in vivo treatment parameters from experimentally-determined in vitro treatment parameters (Discussion, pages 194 and 195). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Castel by using experimentally-determined in vitro treatment parameters in order to determine the in vivo treatment parameters, as taught by Watkin, in the function disclosed by Castel, in order to safely and effectively ablate patient tissue in vivo.

Regarding claims 2, 4, 7 and 9, Applicant argues that Hill does not teach relating in vivo treatment time to in vitro treatment time. However, Examiner maintains that Watkin teaches relating in vivo treatment time to in vitro treatment time and relating in vivo acoustic power to in vitro acoustic power, incorporating blood perfusion and patient tissue density. Arriving at the claimed equations using the disclosure of Castel and the teachings of Watkin and Hill would have required only routine skill in the art. Therefore, at the time the invention was made it would have been obvious to one of ordinary skill in the art to have modified Castel in view of Watkin by using equations equivalent to the

claimed equations for the controller to determine the in vivo treatment time and ultrasound acoustic power, as taught by Hill, in order to effectively ablate the target tissue.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Papapietro whose telephone number is (571) 272-1546. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:
10/824,196
Art Unit: 3739

Page 7

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jacqueline Papapietro
Art Unit 3739



ROY D. GIBSON
PRIMARY EXAMINER